### **DETAILED ACTION**

Applicant is advised that the Non-Final Office Action mailed 28 May 2008 is hereby vacated.

#### Status of Claims

Claims 18, 21-25, 27, 28, 30 and 34-36 are examined herein on the merits for patentability.

### Claim Rejections - 35 USC § 101

Claim 34 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular, claim 34 is drawn to "a sterilizing/disinfecting method", which is not directed to a statutory method. The claim should recite "a method for sterilizing/disinfecting", wherein the method is drawn to sterilizing/disinfecting that has support within the instant specification.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Application/Control Number: 10/539,234 Page 3

Art Unit: 1616

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 1. Claims 18, 21-25, 27, 28, 30, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '122 (WO 01/55122, English language equivalent is US 2003/0109530 which is referred to herein).

### **Applicant claims:**

Applicants claim a dihydrotriazine compound represented by the following formula:

wherein R<sub>1</sub>, R<sub>1</sub>, R<sub>21</sub>, R<sub>3</sub> and R<sub>4</sub> are as defined in the instant claims. Claims 30 and 36 are drawn to an external bactericidal/disinfectant agent comprising the compound of claim 18. Claim 35 is drawn to a method for preparing an external bactericidal/disinfectant agent comprising mixing the compound of claim 18 with a pharmaceutically acceptable additive.

## Determination of the scope and content of the prior art (MPEP 2141.01)

Moinet '122 teaches compounds of the following formula:

$$R_1$$
 $R_2$ 
 $R_3$ 
 $R_4$ 
 $R_4$ 
 $R_4$ 
 $R_4$ 
 $R_5$ 
 $R_6$ 

wherein  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_4$  are chosen independently from the groups including H and  $C_{1-20}$  alkyl,  $C_{3-8}$  cycloalkyl,  $C_{3-8}$  heterocycloalkyl,  $C_{6-14}$  aryl  $C_{1-20}$  alkyl,  $C_{6-14}$  aryl, and  $C_{1-13}$  heteroaryl, wherein each substituents is optionally substituted; and  $R_5$  and  $R_6$  are chosen independently from the groups including H and  $C_{1-20}$  alkyl ([0004]-[0019], [0036], [0039] and [0040]; and claims 1, 2 and 5). Moinet '122 teaches that the pharmaceutical compounds may be provided in forms intended for administration by the parenteral, oral, rectal, permucosal or percutaneous route ([0056]), wherein they are mixed with suitable excipients ([0057]-[0060]; and claim 9).

# Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Moinet '122 do not specifically teach the exact same functional groups at the  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_5$ , and  $R_6$  substituents positions as instantly claimed. However, the functional groups at the substituents positions of Moinet '122 are substantially overlapping with the functional groups at the corresponding substituents positions of the instant claims, with the overlapping functional groups indicated in the table below:

Application/Control Number: 10/539,234 Page 5

Art Unit: 1616

Instant claim 18 Moinet '122

R <sub>1</sub> is an optionally substituted C <sub>1-16</sub> alkyl	$R_1$ and $R_2$ are chosen independently from the groups
	H and C <sub>1-20</sub> alkyl
$R_{21}$ is an optionally substituted $C_{7-16}$ alkyl	R <sub>3</sub> and R <sub>4</sub> are chosen independently from the groups
	H and C <sub>1-20</sub> alkyl
R <sub>1</sub> is H attached to the N at position 1 or 3	H is attached to the N at position 3
$R_3$ and $R_4$ are independently an H or $CH_3$	$R_{\scriptscriptstyle{5}}$ and $R_{\scriptscriptstyle{6}}$ are chosen independently from the groups
	H and C <sub>1-20</sub> alkyl

### Finding of prima facie obviousness

### **Rational and Motivation (MPEP 2142-43)**

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to synthesize compounds that are within the scope of the instant claims because Moinet '122 teaches a genus of compounds that overlap with the instantly claimed genus of compounds.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 18, 21-25, 27, 28, 30 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '530 (US 2003/0109530) for the same reasons as indicated above.

3. Claims 18, 21-25, 27, 28, 30 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moinet '021 (US 7,034,021) for the same reasons as indicated above. Also, see claims 1, 2 and 5 wherein Moinet '021 teach the above drawn compound wherein  $R_1$  and  $R_2$  are independently chosen from only the groups H and  $C_{1-20}$  alkyl,  $R_3$  and  $R_4$  are independently chosen from the groups including H and  $C_{1-20}$  alkyl.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/539,234 Page 7

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**NWS** 

/John Pak/ Primary Examiner, Art Unit 1616